

Please type a plus sign (+) inside this box ☐ +

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

| | | | |
|-------|---|----|---|
| Sheet | 1 | of | 1 |
|-------|---|----|---|

| Complete if Known | |
|------------------------|-------------------------|
| Application Number | 10/071,490 |
| Filing Date | February 7, 2002 |
| First Named Inventor | Marchosky, J. Alexander |
| Group Art Unit | 1615 |
| Examiner Name | Mertz |
| Attorney Docket Number | 60019660-0021 |

| U.S. PATENT DOCUMENTS | | | | | | |
|-----------------------|----------------------|----------------------|-----------------------------------|---|--|---|
| Examiner Initials* | CiteNo. ¹ | U.S. Patent Document | | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document MM-DD-YYYY | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| | | Number | Kind Code ² (if known) | | | |
| bf | 68 | 5,702,716 | | Dunn et al. | 12-30-1997 | |

| FOREIGN PATENT DOCUMENTS | | | | | | | | |
|--------------------------|-----------------------|-------------------------|---------------------|-----------------------------------|---|--|---|----------------|
| Examiner Initials* | Cite No. ¹ | Foreign Patent Document | | | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document MM-DD-YYYY | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | T ⁶ |
| | | Office ³ | Number ³ | Kind Code ² (if known) | | | | |
| bf | 69 | EP | 0312208 | A1 | Ethicon Inc. | 04-19-1989 | | |
| bf | 70 | WO | 91/01720 | | Schlameus et al. | 02-21-1991 | | |
| bf | 71 | EP | 0522569 | A1 | United States Surgical Corporation | 01-13-1993 | | |
| bf | 72 | WO | 98/14222 | | Children's Medical Center Corporation | 04-09-1998 | | |
| BF | 73 | WO | 98/40113 | A1 | University of Florida Tissue Bank, Inc. | 09-17-1998 | | |

| | | | |
|--------------------|-----------------|-----------------|---------|
| Examiner Signature | Blessing Fubara | Date Considered | 9-29-04 |
|--------------------|-----------------|-----------------|---------|

23123987V-1

BEST AVAILABLE COPY

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Please type a plus sign (+) inside this box ☐

Approved for use through 10/31/2002. (01/3/0651-0031)

U.S. Patent and Trademark Office U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

P1052-08A 108-00

TECHNOLOGY

RECEIVED

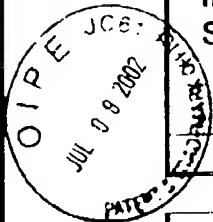
Substitute for form 1449A PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Complete if Known

Application Number 10 071490
Filing Date February 7, 2002
First Named Inventor J. Alexander Marchosky
Group Art Unit
Examiner Name
Attorney Docket Number 60019660-0021



| Examiner Initials* | CiteNo | U.S. Patent Document | | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document MM/DD/YYYY |
|--------------------|--------|----------------------|-------------------------|---|---|
| | | Number | Kind Code (if known) | | |
| bf | 1 | 4141973 | B1 | Balazs | 02/27/1979 |
| | 2 | 4440750 | | Glowacki et al. | 04/3/1984 |
| | 3 | 4642120 | | Nevo et al. | 02/10/1987 |
| | 4 | 4837379 | | Weinberg | 06/06/1989 |
| | 5 | 5073373 | B1 | O'Leary et al. | 12/17/1997 |
| | 6 | 5166331 | B1 | della Vallel et al. | 11/24/1992 |
| | 7 | 5314476 | B1 | Prewett et al. | 05/24/1994 |
| | 8 | 5356629 | B1 | Sander et al. | 10/18/1994 |
| | 9 | 5563124 | | Damien et al. | 10/08/1996 |
| | 10 | 5629287 | A | Brown et al. | 05/1997 |
| | 11 | 5645591 | B1 | Kuberasampath et al. | 07/8/1997 |
| | 12 | 5685716 | B1 | Linkow | 11/11/1997 |
| | 13 | 5711957 | | Patat et al. | 01/27/1998 |
| | 14 | 5755792 | | Brekke | 05/26/1998 |
| | 15 | 5776193 | B1 | Kwan et al. | 07/07/1998 |
| | 16 | 5786327 | B1 | Tam | 07/28/1998 |
| | 17 | 5830493 | | Yokota et al. | 11/03/1998 |
| | 18 | 5837258 | | Grotendorst | 11/17/1998 |
| | 19 | 5894070 | | Hansson et al. | 04/13/1999 |
| | 20 | 5916870 | B1 | Lee et al. | 06/29/1999 |
| | 21 | 5942499 | B1 | Radomsky | 08/24/1999 |
| | 22 | 5948428 | B1 | Lee et al. | 09/07/1999 |
| | 23 | 5958441 | B1 | Oppermann et al. | 09/28/1999 |
| | 24 | 6017940 | A | Petrie et al. | 1/2000 |
| | 25 | 6030635 | B1 | Gertzman et al. | 02/29/2000 |
| | 26 | 6049026 | A | Muschler | 4/2000 |
| | 27 | 6165487 | B1 | Ashkar et al. | 12/26/2000 |

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

*Unique citation designation number. *See attached Kinds of U.S. patent Documents. *Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). *For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. *Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. *Applicant is to place a check mark here if English language translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.



TECH CENTER
JUL 12 2000

RECEIVED

| | | | | |
|----|---------|----|----------------|------------|
| 28 | 6171610 | B1 | Vacanti et al. | 1 2001 |
| 29 | 6214048 | B1 | Ito et al. | 04 10 2001 |

| Examiner Initials* | Cite No. | Foreign Patent Document | | | Name of Patentee or Applicant of Cited Document | Date of Publication of Document MM-DD-YYYY |
|-----------------------|-------------|-------------------------|----------|-------------------------|--|--|
| | | Office | Number | Kind Code (if known) | | |
| PBF | 30 | WO | 91/18558 | A1 | Creative Biomolecules, Inc. | 12/12/1991 |
| | 31 | WO | 93/00050 | A1 | Genetics Institute, Inc. | 01/07/1993 |
| | 32 | WO | 93/20858 | A1 | Fidia S.P.A. | 10/29/1993 |
| | 33 | WO | 94/15653 | | | 07/21/1994 |
| | 34 | WO | 95/13767 | | | 05/26/1995 |
| | 35 | WO | 97/14376 | A1 | Orquest, Inc. | 04/24/1997 |
| | 36 | WO | 97/18842 | A1 | Fidia Advanced Biopolymers S.R.L. | 05/29/1997 |
| | 37 | WO | 97/32591 | | | 09/12/1997 |
| | 38 | WO | 98/22114 | | | 05/28/1998 |
| | 39 | WO | 98/56433 | | | 12/17/1998 |
| | 40 | WO | 00/45870 | A1 | SDGI Holdings, Inc. | 08/10/2000 |
| | 41 | EPO | 754466 | | | 1/22/1997 |

| | | | |
|-----------------------|-----------------|--------------------|---------|
| Examiner Signature | Blessing Fubara | Date Considered | 9/29/04 |
|-----------------------|-----------------|--------------------|---------|



Please type a plus sign (+) inside this box ☐

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

PTO SB 0651-0031

RECEIVED

| | | |
|--|-------------------------------|------------------------|
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i> | Complete if Known | |
| | Application Number | 10-071490 |
| | Filing Date | February 7, 2002 |
| | First Named Inventor | J. Alexander Marchosky |
| | Group Art Unit | Not assigned yet |
| | Examiner Name | Not assigned yet |
| | Attorney Docket Number | 60019660-0021 |

| OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS | | | |
|---|----------|--|----------------|
| Examiner Initials* | Cite No. | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T [†] |
| bf | 42 | Abe et al., "Model-Based Surgical Planning and Simulation of Cranial Base Surgery" (1998) Neurologia Medico-Chirurgica, Vol. 38, pp. 746-751. | |
| | 43 | Bodmeier et al., "Preparation and Evaluation of Drug-Containing Chitosan Beads" (1989) Drug Development Industrial Pharmacy, Vol. 15 pp. 1475-1494. | |
| | 44 | Bruder et al., "Bone Regeneration by Implantation of Purified, Culture-Expanded Human Mesenchymal Stem Cells" (1998) Journal of Orthopaedic Research, Vol. 16, pp. 166-162. | |
| | 45 | Chandy et al., "Chitosan - As a Biomaterial" (1990) Biomat., Art. Cells, Art. Org., Vol. 18, pp. 1-24. | |
| | 46 | Elcin et al., "Neural tissue engineering: Adrenal chromaffin cell attachment and viability on chitosan scaffolds" (1998) Neurological Research, Vol. 20, pp. 648-654. | |
| | 47 | Epply et al., "Free Bone Graft Reconstruction of Irradiated Facial Tissue: Experimental Effects of Basic Fibroblast Growth Factor Stimulation" (1991) Plastic and Reconstruction Surgery, Vol. 88, pp. 1-11. | |
| | 48 | Gäserød et al., "Microcapsules of alginate-chitosan - I quantitative study of the interaction between alginate and chitosan" (1998) Biomaterials, Vol. 19, pp. 1815-1825. | |
| | 49 | Jameela et al., "Glutaraldehyde cross-linked chitosan microspheres as a long acting biodegradable drug delivery vehicle: studies on the <i>in vitro</i> release of mitoxantrone and <i>in vivo</i> degradation of microspheres in rat muscle" (1995) Biomaterials, Vol. 16, pp. 769-775. | |
| | 50 | Katz et al., "Quantification of holographic fringe data: comparison of intact and implanted femurs" (1998) Medical Engineering & Physics, Vol. 20, pp. 114-123. | |
| bf | 51 | Kibbeywhite et al., "Transforming Growth Factor- β Accelerates Osteoinduction in a Craniofacial Only Model" (1993) Growth Factors, Vol. | |

*EXAMINER Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[†] Unique citation designation number. Applicant is to place a check mark here if English language translation is attached.

Burden Hour Statement This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

RECEIVED



TECH CENTER 1800-2

| | |
|----|---|
| | 9, pp. 185-193. |
| 52 | Klokkevold et al., "Osteogenesis Enhanced by Chitosan (Poly-N-Acetyl Glucosaminoglycan) In Vitro" (1996) J. Periodontol. Vol. 67, pp. 1170-1175. |
| 53 | Ko, K., "Superimposed holographic image-guided neurosurgery" (1998) J. Neurosurg., Vol. 88, pp. 777-781. |
| 54 | Miyazaki et al., "Thermally reversible xyloglucan gels as vehicles for rectal drug delivery" (1998) Journal of Controlled Release, Vol. 56, pp. 75-83. |
| 55 | Mori et al., "Effects of chitin and its derivatives on the proliferation and cytokine production of fibroblasts <i>in vitro</i> " (1997) Biomaterials, Vol. 8, pp. 947-951. |
| 56 | Mundy et al., "Stimulation of Bone Formation in Vitro and in Rodents by Statins" (1999) Science, Vol. 286, No. 5446, pp. 1946-1949. |
| 57 | Phillips et al., "Do Growth Factors Stimulate Angiogenesis? A Comparison of Putative Angiogenesis Factors" (1997) Wounds, Vol. 9, pp. 1-14. |
| 58 | Pilloni, "The Effect of Hyaluronan on Mouse Intramembranous Osteogenesis in Vitro" (1997). |
| 59 | Radomsky et al., "Potential Role of Fibroblast Growth Factor in Enhancement of Fracture Healing" (1998) Clinical Orthopaedics and Related Research, Number 355S, pp. S283-S293. |
| 60 | Rao et al., "Use of chitosan as a biomaterial: Studies on its safety and hemostatic potential" (1997) Journal of Biomedical Materials Research, Vol. 34, pp. 21-28. |
| 61 | Sasaki et al., "Stimulation of Osteoinduction in Bone Wound Healing by High-Molecular Hyaluronic Acid" (1995) Bone, Vol. 16, Number 1, pp. 9-15. |
| 62 | Solheim, E., "Osteoinduction by demineralised bone" (1998) International Orthopaedics, Vol. 22, pp. 335-342. |
| 63 | Tabata et al., "Bone regeneration of basic fibroblast growth factor complexed with biodegradable hydrogels" (1998), Biomaterials, Vol. 19, pp. 807-815. |
| 64 | Thomson et al., "Fabrication of biodegradable polymer scaffolds to engineer trabecula bond" (1995) J. Biomater. Sci. Polymer Edn, Vol. 7, pp. 23-38. |
| 65 | Zentner et al., "A holographic study of variations in bone deformations resulting from different headgear forces in a macerated human skull" (1996) The Angle Orthodontist, Vol. 66, pp. 463-472. |

| | | | |
|--------------------|-----------------|-----------------|---------|
| Examiner Signature | Blessing Eubara | Date Considered | 9/29/02 |
|--------------------|-----------------|-----------------|---------|

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**